EXHIBIT Revised 1 HUH
DATE 1-30-09
HB 267

Amendments to House Bill No. 267
1st Reading Copy

Requested by Representative Teresa Henry

For the House Human Services Committee

Prepared by Sue O'Connell
January 30, 2009 (11:32am)

1. Title, page 1, line 9.
Strike: "GOVERNMENTAL"

2. Page 8, line 7 through line 9.
Strike: "(1)" on line 7 through "for:" on line 9
Insert: "(1) A person or entity that complies with the reporting requirements of [section 3] is not subject to civil liability or other civil relief for reporting the information to the board.

(2) Unless a court makes a finding of malice or criminal intent, a person or entity in proper possession of information pursuant to [sections 5 and 6] is not subject to civil liability or other legal or equitable relief for any of the following acts or omissions:"
Renumber: subsequent subsections

3. Page 8, line 10.
Strike: "sections 5 and"
Insert: "section"

4. Page 8, line 11.
Strike: "receiving and using"
Insert: "receiving, using, relying on, or not relying on"

5. Page 8, line 15.
Strike: "inadvertently releasing"
Following: "information"
Insert: "that was released by the board"

6. Page 8.
Following: line 19
Insert: "(4) The immunity provisions of this section do not apply to the board, another state agency, or any political subdivision of the state."

7. Page 11, line 21 through line 24.
Strike: section 17 in its entirety

→ new language

NEW SECTION. **Section 7. Prescription drug database -- immunity.** (1) A person or entity that complies with the reporting requirements of [section 3] is not subject to civil liability or other civil relief for reporting the information to the board.

(2) Unless a court makes a finding of malice or criminal intent, a person or entity in proper possession of information pursuant to [sections 5 and 6] is not subject to civil liability or other legal or equitable relief for any of the following acts or omissions:

(a) furnishing information pursuant to the provisions of [~~sections 5 and~~ section 6];

(b) ~~receiving and using~~ receiving, using, relying on or not relying on information from the database if the information was received as provided for in [sections 5 and 6];

(c) the fact that any information was not furnished;

(d) inaccuracies in the information; or

(e) ~~inadvertently releasing~~ information that was released by the board to a person or entity that was not entitled to receive it.

(2) The provisions of [section 6] do not require a pharmacist or prescriber to obtain information about a patient from the prescription drug database. A pharmacist or prescriber may not be held liable for damages to any person in a civil action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not request or obtain information from the database.

(3) The immunity ~~provisions~~ of this section do not apply to the board, another state agency, or any political subdivision of the state.

NEW SECTION. **Section 8. Database information retention -- destruction.** The board shall retain the information collected for the prescription drug database for up to 3 years, as established by rule. After 3 years, the board shall destroy the information.

NEW SECTION. **Section 9. Administration of prescription drug database.** (1) The board shall hire a licensed pharmacist in good standing in the state of Montana to manage and direct the establishment and maintenance of the prescription drug database.

(2) The board may hire or contract for other professional, technical, or clerical staff as necessary to operate the prescription drug database.

(e) obtaining the information by any means other than provided for in [sections 5 and 6].

(4) A person or entity that is not permitted to receive information from the database pursuant to [sections 5 and 6] and that knowingly or willfully obtains, discloses, or uses the information in the database without written authorization from the patient is liable for a civil penalty of up to $250,000 for each violation.

NEW SECTION. **Section 14. Report to legislature.** The board shall provide a report to the appropriate interim committees of the legislature each interim, including but not limited to information on:

(1) the cost of establishing and maintaining the database;

(2) any grants, gifts, or donations received to assist in establishing and maintaining the database;

(3) how database information was used; and

(4) how quickly the board was able to answer requests for information from the database.

NEW SECTION. **Section 15. Codification instruction.** [Sections 2 through 14] are intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 2 through 14].

NEW SECTION. **Section 16. Severability.** If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

~~NEW SECTION. **Section 17. Two-thirds vote required -- contingent voidness.** Because [section 7] limits governmental liability, Article II, section 18, of the Montana constitution requires a vote of two-thirds of the members of each house of the legislature for passage. If [this act] is not approved by at least two-thirds of the members of each house of the legislature, then [section 7] is void.~~

- END -

Edited

EXHIBIT 1 HUH
DATE 1-30-09
SB 267

Amendments to House Bill No. 267
1st Reading Copy

Requested by Representative Teresa Henry

For the House Human Services Committee

Prepared by Sue O'Connell
January 30, 2009 (8:59am)

1. Title, page 1, line 9.
Following: "IMMUNITY;"
Insert: "PROVIDING AUTHORITY FOR A PILOT PROGRAM;"

2. Page 1, line 15.
Following: "through"
Insert: "12 and"

3. Page 5, line 24.
Strike: "a list of prescription medications"
Following: "provider"
Insert: "a list of prescription drug orders involving controlled substances and drugs of abuse that were prescribed for the patient"

4. Page 5, line 28.
Following: "drug orders"
Insert: "that involve a controlled substance or drug of abuse"

5. Page 5, line 29.
Strike: "5 and 6"
Insert: "4 and 5"

6. Page 6, line 4.
Following: "information"
Insert: "involving a controlled substance or drug of abuse"

7. Page 6, line 18 through line 21.
Strike: section 4 in its entirety
Renumber: subsequent sections

8. Page 7, line 14.
Strike: "drug"
Following: "diversion"
Insert: "of controlled substances or drugs of abuse"

9. Page 7, line 17.
Strike: "drug"
Following: "diversion"
Insert: "of controlled substances or drugs of abuse"

10. Page 7, line 22.
Following: "through"
Insert: "12 and"

11. Page 8, line 10.
Strike: "5 and 6"
Insert: "4 and 5"

12. Page 8, line 12.
Strike: "5 and 6"
Insert: "4 and 5"

13. Page 8, line 16.
Strike: "6"
Insert: "5"

14. Page 9, line 21.
Strike: "prescription drugs"
Insert: "controlled substances or drugs of abuse"

15. Page 9, line 28.
Following: "through"
Insert: "12 and"

16. Page 9, line 29.
Following: "drug orders"
Insert: "that involve a controlled substances or drug of abuse"

17. Page 9, line 30.
Strike: "5"
Insert: "4"

18. Page 10, line 1.
Following: "transmitting"
Insert: "the required"

19. Page 10, line 8 through line 9.
Strike: subsection (7) in its entirety
Renumber: subsequent subsections

20. Page 10, line 22.
Strike: "5 and 6" in two places
Insert: "4 and 5" in two places

21. Page 11, line 1.
Strike: "5 and 6"
Insert: "4 and 5"

22. Page 11, line 3.

Strike: "5 and 6"
Insert: "4 and 5"

23. Page 11.
Following: line 4

"NEW SECTION. **Section 13. Authority to operate pilot program -- limitations -- exceptions.** (1) (a) The board may operate a pilot program in selected counties in which a pharmacy or selected pharmacies volunteer to report all prescription drug order information to the board for the database and monitoring program established in [sections 2 through 12 and 14].

(b) To the extent possible, the board shall select counties for the pilot program that represent both rural and urban areas of the state.

(2) A pilot program established under this section shall follow all of the procedures established in [sections 2 through 12 and 14] for reporting information to the board and obtaining information from the database.

(3) (a) An individual who fills a prescription at a pharmacy participating in the pilot program may request that all of the individual's prescription drug information or selected types of prescription drug information be excluded from the prescription drug database pilot program unless the prescription drug order involves a controlled substance or a drug of abuse.

(b) If the board establishes a pilot program under this section, it shall adopt rules:

(i) establishing how a pharmacy shall notify customers that it is participating in the pilot program and that a customer may opt out of the reporting requirements; and

(ii) describing how an individual may request that any of the individual's prescription drug information that is not subject to the reporting requirements be excluded from the database.

(4) The board may by rule set a fee for participants in the pilot program to cover the additional costs to the board of obtaining the additional prescription drug order information.

(5) If a pilot program is established, the board shall report to the appropriate interim committees of the legislature on the barriers, benefits, and costs reported by pilot program participants."
Renumber: subsequent sections

24. Page 11, line 13.
Following: "through"
Insert: "12 and"

25. Page 11, line 15.
Following: "through"
Insert: "12 and"

26. Page 11, line 21.
Strike: "7"
Insert: "6"

27. Page 11, line 24.
Strike: "7"
Insert: "6"

- END -

BILL NO. HB 267

INTRODUCED BY Teresa K Henry Heidi Schmidt
(Primary Sponsor)
Gary Mc Lane

A BILL FOR AN ACT ENTITLED: "AN ACT CREATING A PRESCRIPTION DRUG DATABASE AND MONITORING PROGRAM; PROVIDING DEFINITIONS; ESTABLISHING PRESCRIPTION DRUG REPORTING REQUIREMENTS; PROVIDING FOR THE USE OF PRESCRIPTION DRUG INFORMATION; PROVIDING FOR FEES TO FUND THE PROGRAM; ALLOWING ADMINISTRATIVE SANCTIONS AND A CIVIL PENALTY FOR FALSELY OBTAINING OR KNOWINGLY DISCLOSING DATABASE INFORMATION; PROVIDING FOR PROVIDING AUTHORITY FOR A PILOT PROGRAM; GOVERNMENTAL IMMUNITY; AMENDING SECTION 37-7-101, MCA; AND PROVIDING FOR CONTINGENT VOIDNESS."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Section 37-7-101, MCA, is amended to read:

"37-7-101. Definitions. As used in parts 1 through 7 of this chapter and [sections 2 through 12 and 14], the following definitions apply:

(1) (a) "Administer" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.

(b) The term does not include immunization by injection for children under 18 years of age.

(2) "Board" means the board of pharmacy provided for in 2-15-1733.

(3) "Chemical" means medicinal or industrial substances, whether simple, compound, or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.

(4) "Collaborative pharmacy practice" means the practice of pharmacy by a pharmacist who has agreed to work in conjunction with one or more prescribers, on a voluntary basis and under protocol, and who may perform certain patient care functions under certain specified conditions or limitations authorized by the prescriber.

(5) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more prescribers that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients.

(6) "Commercial purposes" means the ordinary purposes of trade, agriculture, industry, and commerce,

exclusive of the practices of medicine and pharmacy.

(7) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device based on:

(a) a practitioner's prescription drug order;

(b) a professional practice relationship between a practitioner, pharmacist, and patient;

(c) research, instruction, or chemical analysis, but not for sale or dispensing; or

(d) the preparation of drugs or devices based on routine, regularly observed prescribing patterns.

(8) "Confidential patient information" means privileged information accessed by, maintained by, or transmitted to a pharmacist in patient records or that is communicated to the patient as part of patient counseling.

(9) "Controlled substance" means any substance designated as a dangerous drug pursuant to Title 50, chapter 32, parts 1 and 2.

~~(9)~~(10) "Department" means the department of labor and industry provided for in Title 2, chapter 15, part 17.

~~(10)~~(11) "Device" has the same meaning as defined in 37-2-101.

~~(11)~~(12) "Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for administration to or use by a patient.

~~(12)~~(13) "Distribute" means the delivery of a drug or device by means other than administering or dispensing.

~~(13)~~(14) "Drug" means a substance:

(a) recognized as a drug in any official compendium or supplement;

(b) intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) other than food, intended to affect the structure or function of the body of humans or animals; and

(d) intended for use as a component of a substance specified in subsection ~~(13)(a), (13)(b), or (13)(c)~~ (14)(a), (14)(b), or (14)(c).

(15) "Drug of abuse" means a drug, other than a controlled substance, that is defined by board rule and that has a demonstrated potential for abuse.

~~(14)~~(16) "Drug utilization review" means an evaluation of a prescription drug order and patient records for duplication of therapy, interactions, proper utilization, and optimum therapeutic outcomes. The term includes

but is not limited to the following evaluations:

(a) known allergies;

(b) rational therapy contraindications;

(c) reasonable dose and route administration;

(d) reasonable directions for use;

(e) drug-drug interactions;

(f) drug-food interactions;

(g) drug-disease interactions; and

(h) adverse drug reactions.

~~(15)~~(17) "Equivalent drug product" means a drug product that has the same established name, active ingredient or ingredients, strength or concentration, dosage form, and route of administration and meets the same standards as another drug product as determined by any official compendium or supplement. Equivalent drug products may differ in shape, scoring, configuration, packaging, excipients, and expiration time.

~~(16)~~(18) "Intern" means:

(a) a person who is licensed by the state to engage in the practice of pharmacy while under the personal supervision of a preceptor and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(b) a graduate of an accredited college of pharmacy who is licensed by the state for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(c) a qualified applicant awaiting examination for licensure; or

(d) a person participating in a residency or fellowship program.

~~(17)~~(19) (a) "Manufacturing" means the production, preparation, ~~propogation~~ propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis.

(b) Manufacturing includes:

(i) any packaging or repackaging;

(ii) labeling or relabeling;

(iii) promoting or marketing; and

(iv) preparing and promoting commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

~~(18)~~(20) "Medicine" means a remedial agent that has the property of curing, preventing, treating, or mitigating diseases or which is used for this purpose.

~~(19)~~(21) "Patient counseling" means the communication by the pharmacist of information, as defined by the rules of the board, to the patient or caregiver in order to ensure the proper use of drugs or devices.

~~(20)~~(22) "Person" includes an individual, partnership, corporation, association, or other legal entity.

~~(21)~~(23) "Pharmaceutical care" means the provision of drug therapy and other patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of disease process.

~~(22)~~(24) "Pharmacist" means a person licensed by the state to engage in the practice of pharmacy and who may affix to the person's name the term "R.Ph.".

~~(23)~~(25) "Pharmacy" means an established location, either physical or electronic, registered by the board where drugs or devices are dispensed with pharmaceutical care or where pharmaceutical care is provided.

~~(24)~~(26) "Pharmacy technician" means an individual who assists a pharmacist in the practice of pharmacy.

~~(25)~~(27) "Poison" means a substance that, when introduced into the system, either directly or by absorption, produces violent, morbid, or fatal changes or that destroys living tissue with which it comes in contact.

~~(26)~~(28) "Practice of pharmacy" means:

(a) interpreting, evaluating, and implementing prescriber orders;

(b) administering drugs and devices pursuant to a collaborative practice agreement and compounding, labeling, dispensing, and distributing drugs and devices, including patient counseling;

(c) properly and safely procuring, storing, distributing, and disposing of drugs and devices and maintaining proper records;

(d) monitoring drug therapy and use;

(e) initiating or modifying drug therapy in accordance with collaborative pharmacy practice agreements established and approved by health care facilities or voluntary agreements with prescribers;

(f) participating in quality assurance and performance improvement activities;

(g) providing information on drugs, dietary supplements, and devices to patients, the public, and other health care providers; and

(h) participating in scientific or clinical research as an investigator or in collaboration with other investigators.

~~(27)~~(29) "Practice telepharmacy" means to provide pharmaceutical care through the use of information technology to patients at a distance.

~~(28)~~(30) "Preceptor" means an individual who is registered by the board and participates in the instructional training of a pharmacy intern.

~~(29)~~(31) "Prescriber" has the same meaning as provided in 37-7-502.

~~(30)~~(32) "Prescription drug" means any drug that is required by federal law or regulation to be dispensed only by a prescription subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353).

~~(31)~~(33) "Prescription drug order" means an order from a prescriber for a drug or device that is communicated directly or indirectly by the prescriber to the furnisher by means of a signed order, by electronic transmission, in person, or by telephone. The order must include the name and address of the prescriber, the prescriber's license classification, the name and address of the patient, the name, strength, and quantity of the drug, drugs, or device prescribed, the directions for use, and the date of its issue. These stipulations apply to written, oral, electronically transmitted, and telephoned prescriptions and orders derived from collaborative pharmacy practice.

~~(32)~~(34) "Utilization plan" means a plan under which a pharmacist may use the services of a pharmacy technician in the practice of pharmacy to perform tasks that:

(a) do not require the exercise of the pharmacist's independent professional judgment; and

(b) are verified by the pharmacist.

~~(33)~~(35) "Wholesale" means a sale for the purpose of resale."

NEW SECTION. **Section 2. Prescription drug database and monitoring program -- purpose.** (1) The board shall establish and maintain a prescription drug database for the purpose of improving patient safety by:

(a) making ~~a list of prescription medications~~ a list of prescription drug orders involving controlled substances and drugs of abuse that were prescribed for the patient available to a patient or to a patient's health care provider; and

(b) allowing the board to monitor for possible misuse and diversion of controlled substances and drugs of abuse.

(2) The board shall electronically collect information on prescription drug orders that involve a controlled substance or drug of abuse pursuant to [section 3] and shall disseminate information as allowed in [sections ~~5 and 6~~ 4 and 5].

NEW SECTION. **Section 3. Prescription drug database -- reporting requirements.** (1) Except as provided in subsection (3), each entity licensed by the board as a certified pharmacy or as an out-of-state mail order pharmacy that dispenses drugs to patients with a Montana address shall provide prescription drug order information (involving a controlled substance or drug of abuse) for the database by:

(a) electronically transmitting the information in a format established by the board unless the board has granted a waiver allowing the information to be submitted in a nonelectronic manner; and

(b) submitting the information in accordance with time limits set by the board unless the board grants an extension because:

(i) the pharmacy has suffered a mechanical or electronic failure or cannot meet the deadline for other reasons beyond its control; or

(ii) the board is unable to receive electronic submissions.

(2) The pharmacy submitting information to the prescription drug database assumes all costs associated with submitting the prescription drug order information as required in this section.

(3) This section does not apply to:

(a) a prescriber who dispenses or administers drugs to the prescriber's patients; or

(b) a prescription drug order dispensed to a person who is hospitalized.

~~NEW SECTION. **Section 4. Prescription drug database -- exceptions.** As provided by board rule, an individual may request that all of the individual's prescription drug information or selected types of prescriptions be excluded from the prescription drug database unless the prescription drug order involves a controlled substance or a drug of abuse.~~

NEW SECTION. **Section ~~3~~ 4. Prescription drug monitoring.** The board may review the information in the prescription drug database for possible misuse and diversion of controlled substances and drugs of abuse. The board may provide information about possible misuse or diversion to prescribers and dispensers as allowed by rule.

NEW SECTION. **Section ~~6~~ 5. Prescription drug database -- use -- access.** (1) The board shall establish procedures to protect the privacy and security of information collected, recorded, transmitted, and maintained in the prescription drug database. The information may be disclosed as provided in this section.

(2) The database information is health care information as defined in 50-16-504, is confidential, and may be made available only to the following, upon request:

(a) a person authorized to prescribe or dispense prescription drugs if the person certifies that the information is needed to provide medical or pharmaceutical treatment to a patient who is the subject of the request and who is under the person's care or has been referred to the person for care;

(b) a prescriber who requests information relating to the prescriber's own prescribing information if the prescriber certifies that the requested information is for a purpose in accordance with board rule;

(c) an individual requesting the individual's database information if the individual provides evidence satisfactory to the board that the individual requesting the information is in fact the person about whom the data entry was made;

(d) a designated representative of a government agency responsible for licensing, regulating, or disciplining licensed health care professionals who are authorized to prescribe, administer, or dispense drugs, for conducting investigations related to a health care professional who is the subject of an active investigation for ~~drug~~ misuse or diversion of controlled substances or drugs of abuse;

(e) a peace officer employed by a federal, state, or local law enforcement agency whose duties include enforcing laws relating to drugs if the peace officer has a search warrant for information relating to a person who is the subject of an active investigation by the law enforcement agency related to ~~drug~~ misuse or diversion of controlled substances or drugs of abuse;

(f) an authorized individual under the direction of the department of public health and human services for the purpose of monitoring and enforcing the department's responsibilities under the public health, medicare, or medicaid laws; or

(g) a prescription drug monitoring program in another state if the data is subject to limitations and restrictions similar to those provided in [sections 2 through 12 and 14].

(3) The board shall maintain a record of each individual or entity that requests information from the prescription drug database pursuant to this section.

(4) The board may release information in summary, statistical, or aggregate form for educational, research, or public information purposes. The information may not identify a person or entity.

(5) Information collected in or obtained from the prescription drug database may not be used:

(a) for commercial purposes; or

(b) as evidence in any administrative, civil, or criminal proceeding.

(6) The board shall adopt rules to ensure that only authorized individuals have access to the database

and only to appropriate information from the database. The rules must be consistent with the privacy provisions of the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d, et seq., with administrative rules adopted in connection with that act, and with the privacy provisions of Title 50, chapter 16.

(7) The procedures established by the board under this section may not impede patient access to drugs for legitimate medical purposes.

NEW SECTION. **Section ~~7~~ 6. Prescription drug database -- immunity.** (1) The board, another state agency, or a person or entity in lawful possession of information from the prescription drug database is not subject to liability or action for monetary damages or other legal or equitable relief for:

(a) furnishing information pursuant to the provisions of [sections ~~5 and 6~~ 4 and 5];

(b) receiving and using information from the database if the information was received as provided for in [sections ~~5 and 6~~ 4 and 5];

(c) the fact that any information was not furnished;

(d) inaccuracies in the information; or

(e) inadvertently releasing information to a person or entity that was not entitled to receive it.

(2) The provisions of [section ~~6~~ 5] do not require a pharmacist or prescriber to obtain information about a patient from the prescription drug database. A pharmacist or prescriber may not be held liable for damages to any person in a civil action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not request or obtain information from the database.

NEW SECTION. **Section ~~8~~ 7. Database information retention -- destruction.** The board shall retain the information collected for the prescription drug database for up to 3 years, as established by rule. After 3 years, the board shall destroy the information.

NEW SECTION. **Section ~~9~~ 8. Administration of prescription drug database.** (1) The board shall hire a licensed pharmacist in good standing in the state of Montana to manage and direct the establishment and maintenance of the prescription drug database.

(2) The board may hire or contract for other professional, technical, or clerical staff as necessary to operate the prescription drug database.

NEW SECTION. **Section ~~10~~ 9. Prescription drug database -- advisory group.** (1) The board shall establish an advisory group to provide information and advice about the development and operation of the prescription drug database and monitoring program, including but not limited to information on:

(a) which drugs of abuse should be monitored;

(b) the criteria for reporting information from the prescription drug database to prescribers and pharmacists;

(c) the design and implementation of educational courses about the prescription drug monitoring program;

(d) standards for evaluating the effectiveness of the prescription drug monitoring program; and

(e) administrative rules for putting the prescription drug monitoring program into effect.

(2) The advisory group consists of but is not limited to:

(a) representatives from health care licensing boards that oversee health care providers who have authority to prescribe or dispense drugs;

(b) representatives from associations representing health care professionals who have authority to prescribe or dispense drugs;

(c) representatives from associations that advocate for patients; and

(d) other members as identified by the advisory group.

(3) The board shall establish rules for the conduct of advisory group business.

NEW SECTION. **Section ~~11~~ 10. Prescription drug database -- charges and fees.** (1) Each person licensed under Title 37 who prescribes, dispenses, or distributes ~~prescription drugs~~ controlled substances or drugs of abuse shall pay to the board a nonrefundable fee that is set by rule and that is commensurate with the costs of establishing and maintaining the prescription drug database and monitoring program.

(2) The board may apply for any available grants and may accept gifts, grants, or donations to assist in establishing and maintaining the prescription drug database and monitoring program.

NEW SECTION. **Section ~~12~~ 11. Rulemaking authority.** The board shall adopt rules to carry out and enforce [sections 2 through 12 and 14], including but not limited to rules that:

(1) specify the type of information to be reported on prescription drug orders that involve a controlled substance or drug of abuse;

(2) specify the drugs of abuse that may be monitored as provided in [section ~~5~~ 4];

(3) establish the requirements for transmitting the required prescription drug order information from a pharmacy to the board;

(4) define the electronic format for submission of information;

(5) define the circumstances under which a pharmacy may receive a waiver from the requirement to submit information electronically;

(6) specify the procedure through which a pharmacy may request an extension of the time limit for submitting information;

~~(7) describe how an individual may request that the individual's prescription drug information, except for controlled substances and drugs of abuse, be excluded from the database;~~

~~(8)~~ (9) establish how a person or entity authorized to receive information from the database may submit a request for the information;

~~(9)~~ (8) specify the ways in which the board may use records involving requests for database information to document and report on statistics involving the database;

~~(10)~~ (9) establish procedures for the conduct of advisory group business; and

~~(11)~~ (10) set the fees to be charged for establishing and maintaining the prescription drug database and monitoring program.

NEW SECTION. **Section 13. Unlawful acts -- sanctions -- civil penalties.** (1) A pharmacist who fails to submit prescription drug order information to the board as required by [section 3] must be referred to the appropriate licensing board for consideration of administrative sanctions.

(2) A person or entity authorized to possess prescription drug database information pursuant to [sections ~~5 and 6~~ 4 and 5] who discloses or uses the database information in violation of [sections ~~5 and 6~~ 4 and 5] must be referred to the appropriate licensing board or regulatory agency for administrative sanctions as considered appropriate by that board or agency.

(3) A person or entity may be prosecuted for the following actions involving the prescription drug database:

(a) providing false information to obtain or try to obtain information from the database;

(b) providing information from the database to an unauthorized person;

(c) using or trying to obtain information about a person who is not a patient;

(d) using the information for unauthorized purposes; or

(e) obtaining the information by any means other than provided for in [sections ~~5 and 6~~ 4 and 5].

(4) A person or entity that is not permitted to receive information from the database pursuant to [sections ~~5 and 6~~ 4 and 5] and that knowingly or willfully obtains, discloses, or uses the information in the database without written authorization from the patient is liable for a civil penalty of up to $250,000 for each violation.

→ NEW SECTION. Section 13. Authority to operate a pilot program.... (amendment # 23)

NEW SECTION. **Section 14. Report to legislature.** The board shall provide a report to the appropriate interim committees of the legislature each interim, including but not limited to information on:

(1) the cost of establishing and maintaining the database;

(2) any grants, gifts, or donations received to assist in establishing and maintaining the database;

(3) how database information was used; and

(4) how quickly the board was able to answer requests for information from the database.

NEW SECTION. **Section 15. Codification instruction.** [Sections 2 through 12 and 14] are intended to be codified as an integral part of Title 37, chapter 7, and the provisions of Title 37, chapter 7, apply to [sections 2 through 12 and 14].

NEW SECTION. **Section 16. Severability.** If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

NEW SECTION. **Section 17. Two-thirds vote required -- contingent voidness.** Because [section ~~7~~ 6] limits governmental liability, Article II, section 18, of the Montana constitution requires a vote of two-thirds of the members of each house of the legislature for passage. If [this act] is not approved by at least two-thirds of the members of each house of the legislature, then [section ~~7~~ 6] is void.

- END -